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TECH CENTER #608/2960RT-1578

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Carlos R. Plata-Salaman, Boyu Zhao, Roy E. Twyman

Appln. No.

: 10/081,943

Filed

February 21, 2002

Title

CARBAMATE COMPOUNDS FOR USE IN THE TREATMENT

OF PAIN

Art Unit

1614

Examiner

William R A Jarvis

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

October 10, 2003 (Date of Deposit)

Ellen Ciambrone Coletti

(Name of applicant assignee or Registered Representative)

(Signature)

October 10, 2003

(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE

Dear Sir:

This is a response to the Office Action mailed April 10, 2003.

A petition to extend the time to respond to the pending Office Action by three months is enclosed herewith.

The claims pending and under consideration are claims 1-27.

Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending application no. 10/192, 973, claims 1-26 of copending application no. 09/906,251 and claims 1-40 of copending application no. 10/193,600.

Since this is a provisional rejection, Applicants reserve the right to address this rejection at the appropriate time.

Claims 1-27 are rejected under 35 USC §103(a) as allegedly unpatentable over Hansen, Swerdlow, Beghi or Magnus, each in view of U.S. Patent 6,103,759. This rejection is respectfully traversed.

In the Office Action, it is asserted that

Hansen states, "Antiepileptic drugs (AEDs) as a class have been widely studied and prescribed for the relief of acute and chronic pain. In general, there is the greatest support for the efficacy of AEDs in the treatment of trigeminal neuralgia and diabetic neuropathy and for migraine prophylaxis."; see page 646, column 2. Similarly, Swerdlow teaches that the use of anticonvulsant drugs such as phenytoin and carbamazepine has been successful in the treatment of various types of pain including the claimed trigeminal neuralgia; see pages 51-56 in particular. Beghi teaches the use of anticonvulsant drugs such as carbamazepine and valprioic acid for the treatment of trigeminal neuralgia and other neuropathic pain, migraine, and chronic pain; see pages 64-70 in particular. Magnus teaches the use of the antiepileptic drug gabapentin for the treatment of neuropathic pain, postherpetic neuralgia, diabetic neuropathy, trigeminal neuralgia, and in migraine prophylaxis; see pages S66-S68 in particular.

As recognized in the Office Action under reply, no one of Hansen, Swerdlow, Beghi or Magnus teach or suggest the use of the claimed compounds for the treatment of pain.

In recognition of this deficiency, Choi is relied on in the Office Action for teaching that the claimed compounds are effective anticonvulsive/antiepileptic agents.

In the Office Action, it is asserted that "one skilled in the pharmaceutical arts would have been motivated to treat pain with the claimed carbamate compounds, since at the time of Applicants' invention, antiepileptic drugs, the class of compounds to which the claimed compound were known to belong, had been used to treat various types of pain".

Applicants respectfully submit that to support a combination rejection under §103, not only must the prior art suggest making the claimed invention to one skilled in the art, the prior art must also provide a reasonable expectation of success to one skilled in the art. Both suggestion and expectation must be found in the prior art, not in the Applicants' disclosure. According to the CAFC in <u>In re Vaeck</u>, 20 USPQ2d 1438 (CAFC 1991), what must be considered is:

(1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success...[citations omitted]...Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicant's disclosure." (at 1442).

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Applicants respectfully submit that neither the suggestion nor the reasonable expectation of success are present in the prior art.

Arguably, at most, the cited prior art may be an invitation to experiment. This, however, is not a proper standard for a prior art rejection.

Thus, based on the foregoing, Applicants submit that the claimed invention is patentable over Hansen, Swerdlow, Beghi or Magnus in view of U.S. Patent 6,103,759.

Accordingly, Applicants request that the rejection under 35 USC §103(a) be withdrawn. Applicants respectfully request an allowance and notice of same.

Respectfully submitted,

Ellen Ciambrone Coletti

Reg. No. 34,140

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2359

Dated: October 10, 2003